

## EXAMINER'S AMENDMENT

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/07 and 1/24/08 have been entered.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Amy DeCloux on 2/6/08.

The application has been amended as follows:

**Claims 80-90 and 93-94 have been canceled.**

**Claim 91 has been replaced with the following claim:**

Claim 91. A method for detecting expression of a group of genes consisting of tumor necrosis factor alpha-induced protein (TNFAIP6), calmodulin 1 (CALM1), and laminin, gamma 1 (LAMC1) in a human test individual, said method comprising:

for each gene of said group of genes, detecting and quantifying RNA encoded by said gene in a cartilage sample of said test individual,

comparing said level of RNA to a quantified level of control RNA encoded by said gene in cartilage samples of control individuals, wherein said control individuals are classified as healthy individuals,

Art Unit: 1634

classifying said test individual as being a candidate for having osteoarthritis if, for TNFAIP6 and CALM1, said level of RNA encoded by said gene in said cartilage sample of said human test individual is higher than in said samples of said control individuals, and, for LAMC 1, said level of RNA encoded by said gene in said cartilage sample of said human test individual is lower than in said samples of said control individuals, wherein said gene is differentially expressed in said cartilage sample of said human test individual relative to said samples of said control individuals with a p value of less than 0.05.

**Claim 92 has been amended as follows:**

In line 3 of the claim the word “CALM” has been replaced with ----CALM1----.

In line 6 of the claim and following, the language “using an oligonucleotide of predetermined sequence which is specific only for RNA encoded by said gene in said sample and/or for cDNA complementary to RNA encoded by said gene in said sample” has been DELETED.

In line 16 of the claim the symbol “<” has been deleted and the phrase ---less than--- has been inserted therefore.

In line 18 of the claim the symbol “<” has been deleted and the phrase ---less than--- has been inserted therefore.

**Claim 100 has been amended as follows:**

In line 1 the phrase "diagnosing osteoarthritis" was deleted and the phrase ---determining osteoarthritis may be present--- was inserted therefor.

In line 2 of part (b) of the claim the language “not having osteoarthritis” has been deleted, and the language ---who are healthy individuals--- was inserted therefor.

3. Following this amendment, claims 91, 92, 95-102 remain pending. These claims are allowed.

4. The following is an examiner’s statement of reasons for allowance: The rejections under 112 1<sup>st</sup> paragraph have been overcome by amendment to the claims and in view of the declarations dated 7/17/06 and 1/8/08. The specification provided data that showed that TNFAIP6 and CALM1 are expressed at higher levels in the cartilage of individuals having

osteoarthritis relative to healthy individuals. Likewise, the specification provided data that showed that LAMC1 is expressed at lower levels in the cartilage of individuals having osteoarthritis relative to healthy individuals. The declarations filed replicated and supported the showings in the specification. The rejections for lack of enablement are thus overcome.

5. The declaration dated 1/8/08 is identical to the declaration filed 11/2/07, and so, both have been considered.

***Election/Restrictions--Rejoinder***

6. Claims 91, 92, and 95-102 are allowable. The restriction requirement among methods which require the elected subcombination of genes and methods which require the elected subcombination plus additional subcombinations, as set forth in the Office action mailed on 6/7/05, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.**

7. In view of the withdrawal of the restriction requirement as to the linked inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Art Unit: 1634

8. In an interview with Amy DeCloux on 4/21/08, applicant was informed of the withdrawal of the restriction requirement and indicated a preference that the applicant be passed to allowance, waiving any option to reinstate claims which have been rejoined, if any could have been presented.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Wednesday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

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Art Unit: 1634

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/Juliet C. Switzer/  
Primary Examiner  
Art Unit 1634

April 28, 2008